



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

scw

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,972	09/27/2001	Andrew P. Kramer	20000427.ORI	2533
23595	7590	09/27/2004		
NIKOLAI & MERSEREAU, P.A. 900 SECOND AVENUE SOUTH SUITE 820 MINNEAPOLIS, MN 55402				
			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/964,972

Applicant(s)

KRAMER ET AL.

Examiner

George R Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/16/04.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/27/01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 9-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 8/16/04.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 6, "over a range..." is vague and conflicts with line 2 of the method. The method is for "over a patient's full range" but line 6 has it over a range. It is suggested to delete "a" in line 6 and insert --the full--.

In claim 2, the claim is incomplete for omitting essential method steps amounting to a gap in the method for not having a step of accumulating data. In order to base the template on "accumulated" data, the accumulation of the data must first be positively recited.

In claims 4 and 6, "sensed parameters" lacks antecedent basis.

In claim 13, "a suggested optimum pace timing" makes the claim incomplete since no step has been set forth for suggesting an optimum pace timing.

In claims 17 and 27, "over a desired range" is vague and conflicts with line 2.

In claim 49, line 2, after "collection", --of-- should be inserted.

Art Unit: 3762

In claim 50, line 4, "the intrinsic" is vague and seems to be missing a word.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 13-21, 23, 24, 26-39, 46, and 49-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin (5891176). Bornzin teaches the use of mapping the AV interval to the different activity ranges and with the use of heart rate (the claimed cycle length) to determine an AV interval for programming into the pacemaker. In addition, Bornzin states in column 8 that the samples are taken every hour every day and the first 12 hours of the first day and the second 12 hours of the second day will therefore meet the claimed limitations of "different times in successive 24 hour periods" (it is noted that the claims are open ended "comprising" claims). Also, the A-V interval will be both dynamic and fixed since it is fixed until the next mapping and it is dynamic since it can change after each mapping. Finally, Bornzin states in columns 8 and 9, that the routine may be activated in response to certain conditions, such as the activity level.

Claims 1-8, 13-20, 27-39, and 50-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Turcott et al. Turcott states in columns 6 and 9 that multiple different parameters such as A-V, V-V (the claimed cycle length) or heart rate (also the claimed cycle length) can be

Art Unit: 3762

adjusted over their ranges to determine and program the optimum A-V, V-V, and heart rate. In addition, the programmed A-V, V-V, and heart rate will be both dynamic and fixed since the optimization can run indefinitely or run for a programmed number of times and then fix the parameter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 23, 25, 26, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott et al (or Bornzin for claims 22, 25, 47, and 48).

Turcott (or Bornzin) discloses the claimed invention except for enabling a manual trigger mode for trending conduction times for a specific exercise (claims 22, 25, 47, and 48) and collecting conduction time data based on a sensed parameter (claims 23, 26, and 49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

Art Unit: 3762

modify the pacer optimization routine as taught by Turcott (or Bornzin), with enabling a manual trigger mode for trending conduction times for a specific exercise and collecting conduction time data based on a sensed parameter since it was known in the art that pacer optimization routines use enabling of a manual trigger mode for trending conduction times for a specific exercise, such as a stress test, to provide a programmer/physician a means to start the routine during a stress test to make sure the pacer is operating properly, that the correct pacing parameter is programmed, and that the routine is operated over the complete range of activity and/or heart rates and since it was known that pacer optimization routines use collection of conduction time data based on a sensed parameter to provide an automatic method to start the system when a sensed parameter meets a predetermined condition.

***Allowable Subject Matter***

Claims 40-45 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

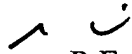
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
George R Evanisko  
Primary Examiner  
Art Unit 3762

9/23/4

GRE  
September 23, 2004